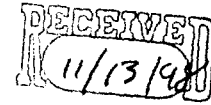




8404 '98 NOV 18 P2:16



November 15, 1998



The Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C. Street S.W.  
Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

- (1) Both the tops and the root of the beet contain folic acid, a vitamin essential for maintenance and repair of the gastrointestinal tract. Both beet tops and tubers also have potassium, helping to balance the high sodium intake of most Americans. Adequate potassium is needed for proper muscle functioning and blood pressure control.\*
- (2) Beet fiber modulates insulin production.\*
- (3) It is known that high homocysteine levels normalize in response to nutrients which aid in the conversion of homocysteine to the amino acid methionine. These include betaine, its precursor choline, the vitamin folic acid, and vitamins B<sub>6</sub> and B<sub>12</sub>. High homocysteine has also been associated with elevated blood cholesterol.\*
- (4) Beets may maintain normal liver function. In the presence of tissue-damaging alcohol, betaine may maintain normal liver metabolism function.\*

These statements are made for a dietary supplement containing beet root powder, vacuum dried beet leaf juice, oat flour, honey and vacuum dried beet root juice. The name of the product is Betafood®.

975 - 0162

Also see docket 975-0163

LET 2440  
62267



**Standard  
Process®**



The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden  
Standard Process Inc.

